

### **REMARKS**

After the foregoing amendment, claims 1-18, 21 and 24-38 are active in the present application. Claim 1 has been amended to incorporate therein the subject matter of claims 19, 20 and 22. No new matter has been added to the application as a result of the amendment to claim 1. Additionally, claims 19, 20, 22 and 23 have been cancelled and claim 21 has been amended to make it dependent from claim 1 rather than from cancelled claim 19. Claims 39-60, which had been the subject of a restriction requirement, have been cancelled, without prejudice to the filing of a divisional application at a later date during the pendency of this application.

#### **Election/Restrictions**

Applicants hereby affirms the election which was made without traverse to prosecute the invention of Group I, claims 1-38. Claims 39-60 have been cancelled, without prejudice to the filing of a divisional application. Applicants confirm that the inventorship with respect to the remaining claims is correct.

#### **Art Rejections**

1. Claims 1-12, 17-18, 24, 26-28, 30 and 36-38 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,096,669 (Lauks et al.). The Examiner states that the Lauks et al. patent discloses a system for conducting medical diagnostic tests comprising a hand held portable instrument that engages a disposable test cell which receives fluid to be diagnostically tested. The Examiner takes the position that the use of notches in the Lauks test cell controls which test is performed when the test cell is inserted into the instrument as called for in claim 1 as originally filed. The Examiner then makes specific comments with respect to the remaining rejected claims. For the reasons as set forth below, the Applicants respectfully traverses the rejection of claim 1 and the above listed dependent claims.

The present invention comprises a system for conducting a plurality of different medical diagnostic tests. The system includes a hand held portable self contained instrument and a series of disposable, single use test cells for receiving fluid to be diagnostically tested. Each of the test cells includes identification information including indicia which is indicative of a particular

diagnostic test to be performed by the electronic instrument upon the fluid contained within the test cell. The indicia on a particular test cell are unique to that particular test cell so that no two test cells contain the same indicia. This feature is particularly important to the present invention as it precludes a test cell from ever being used twice. Each test cell is sized and shaped for engagement by the instrument. The instrument includes a reader for reading the indicia on the test cell prior to engagement of the test cell by the instrument. The diagnostic test to be performed is selected by the instrument based upon the identification information obtained from the indicia on the test cell.

Claim 1 has been amended to clarify that it is the indicia on the test cell which is read by a reader included in the instrument prior to the test cell being engaged by the instrument. Claim 1 has been further amended to stress that the indicia on a particular test cell is unique to that test cell so that no two test cells contain the same indicia.

The Lauks et al. patent discloses an instrument for performing a variety of electrochemical measurements on blood or other fluids drawn into a disposable device. The disposable device includes a series of notches (28, 30, 32 and 34) which are utilized by the instrument after the disposable device is inserted into the instrument to indicate the particular test to be performed on the blood or other fluid within the disposable collection device. Significantly, the Lauks et al. patent contains no reader other than the reader which is utilized to decode the notch pattern on the device after the device has been inserted into the instrument. Thus, the Lauks et al. patent does not disclose the concept of indicia on the test cell or device nor does it disclose or suggest that the instrument include a reader for reading the indicia on the test cell prior to engagement of the test cell by the instrument as called for in claim 1 as amended. Further, because the Lauks et al. patent relies upon the position of four notches for identifying a test to be performed, the maximum combination of notches is very limited. Thus, there is no disclosure or suggestion in the Lauks patent that the notches could serve the function of providing indicia on a particular test cell which is unique to that test cell so that no two test cells contain the same indicia as called for in claim 1 as amended. Accordingly, it is respectfully submitted that claim 1, as amended, distinguishes patentably over the Lauks et al. patent and the rejection of claim 1 under 35 U.S.C. § 102(b) should be withdrawn.

Dependent claims 2-12, 17, 18, 24, 26-28, 30 and 36-38 also distinguish patentably over the Lauks et al. patent at least by virtue of their dependency from claim 1. Accordingly, it is

respectfully submitted that the rejection under 35 U.S.C. § 102(b) of all of these dependent claims should also be withdrawn.

2. Claim 13-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lauks et al. patent in view of U.S. Patent No. 4,797,188 (Tomita). The Examiner states that the Lauks et al. patent teaches all of the limitations of claims 13-16 other than the detailed structure for the test cell. The Examiner further states that the Tomita patent teaches an alternate cell for monitoring the constituents in aqueous samples that are typical of a test cell for measuring concentrations of things, such as potassium, which includes an electrolyte. The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to utilize the teachings of Tomita in connection with the apparatus of Lauks et al. The Applicants respectfully traverses the rejection of claims 13-16.

As discussed in detail above, the Lauks et al. patent does not disclose or suggest the features of claim 1 with respect to each particular test cell including indicia unique to that test cell so that no two test cells contain the same indicia and the instrument including a reader for reading the indicia on the test cell prior to engagement of the test cell by the diagnostic instrument. The Applicants has carefully reviewed the Tomita patent and have not identified any disclosure, teaching or suggestion in the Tomita patent regarding the use of such unique indicia on each test cell or the reading of the indicia on the test cell prior to insertion of the test cell into the diagnostic instrument. Since neither of the references cited by the Examiner discloses teaches or suggests these required features of claim 1, as amended, it is respectfully submitted that claims 13-16 distinguish patentably over the combination of the Lauks et al. and Tomita patents at least by virtue of their dependency from claim 1. Accordingly, it is respectfully submitted that the rejection of claims 13-16 under 35 U.S.C. § 103(a) should be withdrawn.

3. Claims 20-23 and 35 (and claim 19 in the alternative) were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lauks et al. patent in view of U.S. Patent No. 5,690, 893 (Ozawa et al.). Claims 19, 20, 22 and 23 have been cancelled and the subject matter thereof has been incorporated into claim 1. Accordingly, Applicants will address this rejection as it relates to claim 1, as amended.

The Examiner states that the Lauks et al. patent sets forth all of the limitations of the claims but not explicitly the use of a reader or bar code. The Examiner further states that Ozawa teaches the use of other indicia for identifying details about a test cell including bar codes (col. 1,

lines 18-33 and col. 5., line 59 through col. 6, line 14). The Examiner concludes it would have been obvious to one of ordinary skill in the art to utilize the teachings of the Ozawa et al. patent for the system of the Lauks et al. patent in order to further improve measurement accuracy. The Examiner specifically states that if the information contained calibration or correction information unique to a particular test cell, then every identification would be unique. For the reasons as set forth below, the Applicants respectfully traverses this rejection as it relates to claim 1.

The Examiner points to col. 1, lines 18-23 of the Ozawa et al. patent to support his rejection. It is true that this portion of the Ozawa patent discloses that it is known that a reagent vessel be provided with a bar code representing the kind and lot number of a reagent included in the vessel. However, there is no disclosure or teaching in the Ozawa et al. patent which would in any way suggest that the bar code be read by an instrument prior to insertion of the reagent vessel as is called for in claim 1, as amended. The Examiner further points to the language at col. 5, line 59 through col. 6, line 14 as suggesting that a great deal of additional information could be incorporated into the test cell. However, there is nothing to tie that information to the bar code or any other indicia applied to the sensor or test cell indicia. Instead, it is respectfully submitted that the information described at the bottom of col. 5 and extending onto the top of col. 6 of the Ozawa et al. patent is actually stored within a non-volatile memory of the sensor or test cell (see col. 6 beginning at line 15 and other places throughout the Ozawa et al. patent.). Accordingly, it is respectfully submitted that contrary to the suggestions of the Examiner, there is no disclosure, teaching or suggestion in the Ozawa et al. patent of the use of indicia on a particular test cell which is unique to that test cell in combination with an instrument having a reader for reading the indicia on the test cell prior to engagement of the test cell. Accordingly, it is respectfully submitted that claims 21 and 25 distinguish patentably over the combination of the Lauks et al. patent and the Ozawa et al. patent at least by virtue of their dependency from claim 1, as amended, and that the rejection should therefore be withdrawn.

4. Claims 25 and 29 and 27 and 28 in the alternative were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lauks et al. patent in view of U.S. Patent No. 4,798,705 (Jakobowicz et al.). Similarly, claims 31-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lauks et al. patent in view of U.S. Patent No. 5,405,510 (Betts et al.). Each of these claims depends directly or indirectly from claim 1, as amended. It is respectfully

submitted that the Jakobowicz et al. and Betts et al. patents do not disclose, teach or suggest the features discussed above with respect to claim 1, as amended, which distinguish claim 1 from the Lauks et al. patent. In particular, neither the Jakobowicz et al. nor Betts et al. patent disclose or suggest the concept of having indicia on a particular test cell which is unique to that test cell so that no two test cells contain the same indicia or the concept of the instrument including a reader for reading the indicia on the test cell prior to engagement of the test cell by the instrument for selection of the particular diagnostic test to be performed. Accordingly, it is respectfully submitted that the rejections of claims 25, 27-29 and 31-34 should be withdrawn.

In view of the foregoing amendment and discussion, it is respectfully submitted that the present application including claims 1-18, 21 and 24-38 is in condition for allowance and such action is respectfully solicited.

Respectfully submitted,

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(Date)

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